

correction



IFW

Application/Control Number: 10/803,521
Art Unit: 1611

Page 5

effects. The skilled artisan would have had a reasonable expectation of successfully determining the dosage of midazolam and the time required to treat acute by nasally administering midazolam.

Claim 29 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 8-11, 19, 21, 23, 24, and 27 of '271 and Schweizer as applied to claims 11-15, 18, and 27 as above, and further in view of Knoester et al. (Br. J. Clin. Pharmacol. 53, 501-507).

The combined references fail to teach a midazolam intranasal composition comprising no less than 25 mg/ml of midazolam or its salts.

Knoester teaches administering intranasal preparation comprising 5mg/mL in a mixture of water and propylene glycol. See p. 502, Methods. The reference teaches that the dose of intranasal midazolam for treating seizure activity is based on body weight, and increasing the concentration of midazolam reduces the total volume of fluid to be delivered, thereby maintaining the bioavailability and efficacy of the drug. See p. 502, first column, first 2 paragraphs.

It would have been obvious to one of ordinary skill in the art to modify the teachings of the combined references by increasing the concentration of midazolam or its salts as motivated by Knoester, because the latter teaches that increasing the midazolam concentration to meet the required dose is more effective than increasing the amount of the fluid.

Knoester et al. do NOT teach 5 mg/ml, but they teach an intranasal spray containing 2.5 mg midazolam in 90 μ l propylene glycol and water, and this means the midazolam intranasal composition of Knoester et al. comprises 27.8 mg/ml.

Correction

Application/Control Number: 10/803,521
Art Unit: 1611



Page 7

Claims 17, 20, and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of '979 application and Schweizer as applied to claims 11-15, 18, and 27 as above, and further in view of Fisgin et al. (J. of Child Neurol. Dec. 2000).

The copending application and Schweizer do not teach the time required for midazolam to take effects.

Fisgin discloses a method of rapidly treating acute seizures of children in 5 minutes by nasally administering midazolam (5 mg/mL). See abstract.

It would have been obvious to a skilled artisan to formulate and administer the midazolam nasal spray of the combined references as motivated by Fisgin because the latter teaches the time required for midazolam that is nasally administered to take effects. The skilled artisan would have had a reasonable expectation of successfully determining the dosage of midazolam and the time required to treat acute by nasally administering midazolam.

Claim 29 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of '979 application and Schweizer as applied to claims 11-15, 18, and 27 as above, and further in view of Knoester et al. (Br. J. Clin. Pharmacol. 53, 501-507).

The combined references fail to teach a midazolam intranasal composition comprising no less than 25 mg/ml of midazolam or its salts.

Knoester et al. do NOT teach 5 mg/ml, but they teach an intranasal spray containing 2.5 mg midazolam in 90 μ l propylene glycol and water, and this means the midazolam intranasal composition of Knoester et al. comprises 27.8 mg/ml